STATE OF NEW HAMPSHIRE
BOARD OF PHARMACY

April 21, 2004

A **special meeting** of the New Hampshire Board of Pharmacy was held on **April 21, 2004** at the Board office, 57 Regional Drive, Concord, New Hampshire. The purpose for the meeting was to review existing Rules of the Board and to draft amendments and, where necessary, propose new sections in preparation for the rulemaking process. Also, considered for amendments were various RSA's in Chapters 318 and 318-B. The meeting was **called to order at 8:12 a.m.** with President Margaret E. Hayes presiding.

I. ROLL CALL - AGENDA REVIEW - ANNOUNCEMENTS

PRESENT

Margaret E. Hayes, President
Kristina Genovese, Vice-President
George L. Bowersox, Treasurer
Sandra B. Keans, Secretary
Vahrij Manoukian, Member
Ronald L. Petrin, Member

ALSO PRESENT

Paul G. Boisseau,
Executive Secretary
Jeffrey S. Poirier,
Compliance Investigator

II. WORK SESSION

A. **For legislative consideration, the following definitions in Chapter 318:1 were reviewed:**

RSA 318:1 Definitions in this chapter:

V. "Dispense" means to distribute, leave with, give away, dispose of, deliver, or sell one or more doses of a drug **that will be administered or taken at a later date, time or location** and shall include the transfer of more than a single dose of a medication from one container to another and the labeling or otherwise identifying a container holding more than a single dose of a drug.

XIX. "Supervision" means under the direct charge or direction and does not contemplate absence of the person responsible for providing such supervision, except where permitted by rules of the board under RSA 318:5-a, XIV. ***No changes recommended.***

B. **Ph 303.02 Licensing Only the Prescription Department**

(d) A licensed pharmacist shall be on duty at all times when the prescription department is open to the public~~.~~ **and ~~D~~during** any absences by the pharmacist, the prescription department shall be secured~~.~~ **except as is provided in Ph 704.01(b).**

(h) No prescription, new or refill, shall be left with or accepted by clerks**, pharmacy technicians or pharmacy interns** when the prescription department is closed~~.~~ **except as is provided in Ph 704.01(b).**

(j) No telephone prescriptions, new or refill, shall be accepted by clerks**, pharmacy technicians or pharmacy interns** when the prescription department is closed~~.~~ **except as is provided in Ph 704.01(b).**

C. **Ph 308.05 Other Licensing Fees.** The annual licensing fee for federally funded clinics under the direction of the department of health and human services shall be ~~$50.~~ **$150 and for drug abuse treatment centers shall be $200.**

D. **PART Ph 600 STANDARDS FOR LIMITED RETAIL DRUG DISTRIBUTORS**

Ph 600.01 License required

(a) No person shall act as a Limited Retail Drug Distributor, as defined in RSA 318:1,VII-a, without first obtaining a license to do so from the board according to RSA 318:51-b. No license shall be issued or renewed for a limited retail drug distributor unless the same shall be operated in a manner prescribed by law and according to the rules adopted by the board of pharmacy with respect thereto.

(b) Separate licenses shall be required for each site owned and operated by the limited retail drug distributor.

(c) The board shall provide, on an annual basis, a license renewal to all licensed limited retail drug distributors.

(d) The prescribed fee for annual and renewal licenses for limited retail drug distributors shall be:

Clinics under contract with DHHS	$150
Methadone Maintenance/Detox. Treatment Ctrs.	$200

Ph 600.02 Obtaining and Filing a License Application

Applications for licensure of limited retail drug distributors may be obtained from, and shall be filed at, the board office, identified in Ph 103.03.

Ph 600.03 Application Contents.

(a) The applicant for licensure shall supply, on form (MM-1), at least the following information:

1. Name of the facility
2. Address of the actual location where business is conducted.
3. Identification of ownership
4. Hours of operation
5. List of persons with access to the drug supply
6. Signature of the person responsible for the licensed location and date signed.
7. Identity of the consultant pharmacist
8. Identity of the medical director

(b) The applicant shall also submit a scaled drawing of the facility.

(c) It shall be the responsibility of the applicant to supplement the application with any certificates, affidavits, plans, documents or other information sufficient to show full compliance with all of the requirements of part Ph 600.

(d) If the applicant is a corporation, or the limited retail drug distributor will be operated under a corporate name, a certificate from the secretary of state attesting to the documents creating the corporate person and any amendment(s) thereof to the certificate of incorporation, or authorizing it to do business in the state of New Hampshire under the corporate name.

(e) If the applicant proposes to hold, store or dispense controlled substances (Methadone Maintenance/Detox. Facility), the application must be supplemented with the following information:

1. A brief description of the security system.
2. A list of all persons with access to the controlled substances.
3. It shall be the responsibility of the applicant to supplement the application with any certificates, affidavits, plans, documents or other information sufficient to show full compliance with all of the requirements for operation of a drug abuse treatment facility.

(f) If the application is for a Methadone Maintenance/Detox. Facility, the current registration number issued by FDA.

Ph 600.04 Consultant Pharmacist

All applicants licensed under the provisions of RSA 318:51-b, shall have a written contract with a pharmacist, licensed in NH, to serve as a consultant on all matters relating to procurement, storage and dispensing of legend drugs.

Ph 600.05 Changes in Supporting Information:

The applicant shall notify the board, immediately, of any changes of information from that which was submitted on the original application, pursuant to Ph 600.03.

Ph 600.06 Renewal Applications:

(a) The license period shall be from July 1 thru June 30, of the following year.

(b) Applications for renewal of a license to operate as a Limited Retail Drug Distributor shall consist of the application as described in Ph 600.03 and the prescribed fee as indicated in Ph 600.0(d).

Ph 600.07 Temperature

The temperature in any area wherein drugs are stored, manufactured, compounded or dispensed, shall, at all times be in compliance with the standards established by the United States Pharmacopoeia.

Ph 600.08 Quarantine

Any drug, which is adulterated or misbranded shall be removed from the routine stock and held in a specifically designated secure area of the facility pending proper and safe disposition.

Ph 600.09 Space:

Pharmaceuticals shall be housed in a well-lighted and ventilated room or department with clean and sanitary surroundings.

Ph 600.10 Security

That portion of the facility wherein drugs are stored, compounded or dispensed, shall be lockable so as to prevent entry into that area by any person or persons without the knowledge of the authorized individuals on duty, or when the facility is not open.

(a) If the facility contains controlled substances, it shall be equipped with a suitable alarm system (as referenced in Ph 309.06).
(b) Methadone Maintenance/Detox facilities shall ensure that all access from outside their premises is secure. This shall include, but not limited to, the installation of adequate lighting at the outside perimeter of the premises.
(c) All controlled substances shall be stored pursuant to the security provisions outlined in 21 CFR 1301.72(a).
(d) The consultant pharmacist shall visit, at least monthly, all areas of the facility where drugs are stored to ensure that they are properly labeled, have not reached their expiration date and show no signs of deterioration. Any substance not conforming to these standards shall be removed from stock.
(e) A written record of each monthly inspection, specified in (3) shall be maintained on site and available to the board upon request.
(f) The pharmacist shall ensure that the areas specified in (3) above are in compliance with federal and state drug laws relative to security, drug distribution and product tampering.
(g) The consultant pharmacist shall develop a distribution system, which shall prevent drug diversion. Where applicable, the inventory of all schedule II controlled substances and other controlled drugs as required by local, state and federal law stored in any area of the facility, shall be checked by 2 persons at least every 24 hours and accountability records shall be maintained.

Ph 600.11 Dispensing Practices

(a) Drugs shall be dispensed only by or in the presence of and under the immediate supervision of a pharmacist, physician, advanced registered nurse practitioner, physician assistant, or registered nurse, as identified in RSA 318:42 VII (a), in compliance with local, state and federal pharmacy-related laws and rules.
(b) No finished prescription shall be left outside of the drug room of the facility for pick-up when the licensed practitioner is not present to provide immediate supervision.
(c) In the case of Methadone Maintenance/Detox Facilities, all drugs and drug products must remain in the medication room at all times.

Ph 600.12 Deliveries

(a) All drug order deliveries containing prescription drugs shall be delivered only when a licensed practitioner is on the premises in order to secure such drug orders.

(b) In the case of Methadone Maintenance/Detox Facilities, drug deliveries may be accepted only by the licensed practitioner or other individuals identified according the requirements of 21 CFR 1301.74(h)

Ph 600.13 Access to Drug Supply

Only the pharmacist, physician, advanced registered nurse practitioner, physician assistant or registered nurse, as identified in RSA 318:42 VII (a), shall have access to the drug supply.

Ph 600.14 Dispensing Records

(a) A readily retrievable record shall be made of all administration or dispensing of prescription drugs from the facility.

(b) This record shall be separate from the patients medical record and shall include:
1. Name and address of the patient.
2. Date of administration or dispensing.
3. Name, strength and quantity of drug(s) administered or dispensed.
4. Identity of the prescriber.
5. Signature of the person administering or dispensing.

(c) Methadone Maintenance/Detox Facilities must maintain a dispensing log containing the following information:
1. Name of substance
2. Strength of substance
3. Dosage form
4. Date administered
5. Adequate identification of patient
6. Amount consumed
7. Amount & dosage form taken home
8. Dispenser's signature

(d) Records of administrations and dispensing shall be maintained for a period of 4 years. Such records shall be open to inspection by the pharmacy board and its agents.

Ph 600.15 Prescription Labels

(a) Whenever an authorized practitioner dispenses a controlled or non-controlled drug, he/she shall affix to the container in which such drug is dispensed, a label showing at least:

1. Name and address of the facility.
2. Name of the patient.
3. Date dispensed.
4. Name, strength and quantity of drug dispensed.
5. Directions for use.
6. Name of the prescribing practitioner.
7. Name or initials of the dispensing practitioner.
8. All pertinent auxiliary labels.

Ph 600.16 Labeling Exemption

The labeling requirements, as specified in Ph 600.11, are exempted when medication is being administered, for immediate consumption, such as in a Methadone Maintenance/Detox Facility.

Ph 600.17 Violations

Any person who distributes legend drugs according to RSA 318:51(b) and the provisions of Ph 600, shall be subject to disciplinary action as provided in RSA 318:29.

E. **Ph 702.05 Limitations on Access**

(a) **Except as provided in Ph 704.01(b), ~~N~~no** pharmacy shall be open unless a pharmacist is on duty in the pharmacy. At all times during which a pharmacist is not on duty in the pharmacy, all entry to the pharmacy shall be barred by locked doors.

F. **Ph 704.01 Presence of Pharmacist**

(a) Legend drugs and devices shall be dispensed only in the presence of and under the immediate supervision of a pharmacist~~.~~ **except as provided in (b).**

(b) Whenever the pharmacy is staffed by a single pharmacist, the pharmacist may take a lunch/rest break for a period of up to 30 minutes without closing the pharmacy and removing pharmacy technicians and pharmacy

interns from the pharmacy if the pharmacist reasonably believes that the security of the prescription drugs will be maintained in his or her absence.

1. **The lunch break should be taken no later than six (6) hours from the beginning of the shift, or halfway through the shift, whichever occurs first.**

2. **Lunch breaks should be scheduled as close as possible to the same time each day in order for the patients to become familiar with the approximate times of lunch breaks.**

3. **Lunch breaks are encouraged but not mandatory and are a part of the total hours worked each week.**

4. **The pharmacist shall remain on the store premises during the lunch break and be available for "emergencies". Emergencies will be defined by the patient.**

5. **If two or more pharmacists are on duty, the pharmacists shall stagger their lunch breaks so that the pharmacy is not left without a pharmacist on duty.**

6. **Whenever the pharmacist temporarily leaves the prescription department for a lunch break, a sign indicating that there is no pharmacist on duty shall be conspicuously displayed in full view of patients approaching the prescription department service area. The signage shall also indicate the time when the pharmacist is to return.**

7. **Only pharmacy technicians or pharmacy interns authorized by the pharmacist on duty may remain in the pharmacy while the pharmacist is on lunch break.**

8. **During such times that the pharmacist is temporarily absent from the pharmacy, duly authorized (by the pharmacist on duty) pharmacy technicians or pharmacy interns may continue to perform non-discretionary duties as delineated by the pharmacist. However, all duties performed by the technicians or interns shall be reviewed by the pharmacist upon his or her return from break.**

9. **When a pharmacist is not in the pharmacy, there shall be no dispensing (sale) of new prescriptions (that the pharmacist has**

checked and are waiting to be picked up) nor shall counseling be provided by the pharmacy technician or pharmacy intern.

10. **New (written) prescriptions, presented in person by the patient or his agent, may be accepted by the pharmacy technician or pharmacy intern and the processing of that prescription, up to the final check, may occur during the absence of the pharmacist. However, no new prescriptions may be dispensed (sold) until the final check is completed by the pharmacist on his or her return.**

11. **New prescriptions conveyed by telephone shall not be accepted and the caller should be instructed to call back or a telephone number obtained for the pharmacist to call upon his or her return.**

12. **During the pharmacist's absence, prescription refills which have been previously prepared and checked by a pharmacist may be picked up by the patient or his agent. The pharmacy technician or the pharmacy intern must offer counseling by the pharmacist to the patient. If the patient has no questions, the sale may proceed as normal with the patient signing for the refusal. Should the patient desire counseling, he or she should be asked to wait for the pharmacist to return from break or, alternatively, asked to leave a telephone number for the pharmacist to call that afternoon.**

13. **Telephone refill orders as well as refill requests presented, in person, by the patient or his agent, may be accepted by the pharmacy technician or intern and such refill orders may be processed by the technician or intern up to the final check. However, no such refill orders shall be dispensed (sold) until the final check is completed by the pharmacist on his or her return from break.**

14. **A pharmacist who takes a lunch break in compliance with this protocol shall not be subject to NH State Board of Pharmacy disciplinary action or Board citation for acts that he or she did not authorize and that he or she, by the exercise of reasonable care, could not have prevented during his or her absence.**

15. **If in the professional judgment of the pharmacist, for reasons of security or otherwise, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy and remove all pharmacy**

technicians and pharmacy interns from the pharmacy during his or her absence and a suitable sign informing the public of the pharmacist's return shall be conspicuously posted.

G. **Ph 701.02 Definitions.**

Except where the context makes another meaning manifest, the following words mean:

(a) "Adulterated drug" means any drug:

(1) That is contaminated, decomposed, deteriorated, sub-potent, super-potent, or otherwise unsafe for administration to man or other animals;

(2) Which has been manufactured, composed, prepared, stored, or dispensed in such a manner which may cause it to be contaminated, decomposed, deteriorated, sub-potent, super-potent, or otherwise unsafe for administration to man or other animals;

~~(3) Whose labelled expiration date has been exceeded by more than 30 days; and~~

~~(4)~~**(3)** Which can be defined as an adulterated drug under the provisions of RSA 146 or federal law.

H. **PART Ph 707 DISPOSAL AND DESTRUCTION OF CONTROLLED DRUGS**

Ph 707.01 Controlled Drug Destruction. Any person authorized to possess controlled drugs and desiring to dispose of such drugs may request ~~destruction of the drugs by the board.~~ **authorization from the board to destroy such drugs.**

Ph 707.02 Request for Destruction.

(a) A request to destroy controlled drugs shall be in writing and signed by a duly authorized person as defined in (b) below. The written request ~~may be presented to a board representative on site, but the destruction process shall not proceed until the board representative has the written request in his or her possession.~~ **shall be conveyed to the board office and the destruction process shall not proceed until the authorization is received by the person who made the request.**

(b) Personnel authorized to sign a request for controlled drug destruction may include:

(1) ~~Pharmacists~~ **Pharmacist-in-charge**, practitioners or their designated agents;

(2) Administrators of health care institutions or their designated agent or

agents;
(3) Agents of the superior court;
(4) County attorneys;
(5) Director, New Hampshire state police;
(6) Chiefs of local police departments; and
(7) Director, New Hampshire division of public health services or his/her designated agent(s).

(c) The written request shall not be required when a consultant pharmacist, acting as an agent of the pharmacy board, destroys controlled drugs in a licensed nursing home.

III. ADJOURNED AT 9:30 A.M.

Respectfully submitted,

Sandra B. Keans
Secretary
FOR THE BOARD